

*Prepared for EPA article -
Judge or Advocate*

BACKGROUND

1. The Environmental Protection Agency ("EPA") was created in 1970. See Reorganization Plan 3 of 1970, cited at 40 C.F.R. 81.1. At no time has the EPA had statutory authority to regulate indoor air quality; at no time has the EPA had authority to regulate indoor air quality in the workplace.

2. Although the SAB traces the roots of its existence to the early 1970s, in 1977 it was formally established by statute under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Specifically, the statutory authority for the SAB is 42 U.S.C. § 4365. Under this statute, the SAB is to be established by the Administrator of the EPA and is to be comprised of at least nine (9) members, one of whom is designated as Chairman. The members of the SAB "shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred" to the SAB. The SAB is authorized to constitute such member committees and investigate panels as the EPA Administrator and the SAB find necessary.

3. The legislative history of the SAB enabling statute is found at 1977 U.S. Code Cong. & Admin. News, 3283-3298. This history confirms that the function of the SAB is advisory only, that its purpose is to provide the Administrator with expert, independent, scientific review and appraisal of EPA science goals

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and needs, and major programs. The legislative history specifies that the purpose of the SAB is to "review conflicting claims and advise the Administrator on the adequacy and reliability of the technical basis for rules and regulations. * * * The Board is not intended as a forum to be used by outside interests to criticize the workings of the Agency." Id. at 3295.

4. Although the SAB would constitute an "advisory committee" within the meaning of the Federal Advisory Committee Act, 5 U.S.C. App. 2, § 3(2), from its Charter, it is apparently that the SAB does not function as a body of the whole. Rather, matters assigned to the SAB are, in turn, referred by the SAB Chairman to the SAB committee or investigative panel appropriate to revise that matter. The committee or panel then reports to the Administrator through the Executive Committee of the SAB.

5. According to its Charter, the SAB Executive Committee is comprised of a Chairman, the eight Chairpersons from the standing committees, and possibly some additional members. The SAB Executive Committee and each of the eight standing committees (and perhaps the investigative panels) would constitute "advisory committees" within the meaning of the Federal Advisory Committee Act ("FACA").

6. In 1986 Congress passed the Radon Gas and Indoor Air Quality Research Act of 1987, Title IV, Superfund Amendments

and Reauthorization Act of 1987, 42 U.S.C. § 7401 (the "Radon Act") which provided limited authority for the EPA to establish a research program with respect to radon gas and indoor air quality, including research relating to the effects of indoor air pollution and radon on human health. See 42 U.S.C. § 7401(a) and (b)(2). The Act required the Administrator to establish an Advisory Committee comprised of individuals representing Federal agencies and an advisory group comprised of individuals representing the States, the scientific community, industry and public interest organizations to assist him in carrying out the research program. 42 U.S.C. § 7403(c). The Act also specifically prohibited the Administrator from regulating any indoor air pollutant unless authority is conferred by another statute.

7. The Radon Act prescribes both review and advisory committee functions. Section 403(c) requires the EPA Administrator to establish two advisory committees: (1) An advisory committee comprised of representatives of each of the Federal agencies concerned with various aspects of indoor air quality, and (2) another committee comprised of representatives of the States, the scientific community, industry, and public interest organizations. These committees are to assist the EPA Administrator in carrying out the EPA's research program for radon gas and indoor air quality. Section 403(d) designates the EPA Science Advisory Board to comment

to Congress with respect to the EPA's implementation plan pertaining to research under this Act.

8. Upon passage of the Radon Act, the SAB's then existing Indoor Air Quality Research Review Panel was renamed the Indoor Air Quality/Total Human Exposure Committee ("IAQTHEC"). In a report to Congress entitled "Review of the EPA Indoor Air Quality Implementation Plan," dated December 15, 1988, the IAQTHEC identified itself as being the SAB committee designated to review the EPA's Implementation Plan under § 403(d) of the Radon Act and, also, to be the advisory committee specified under § 403(c) of the Radon Act to perform special interest functions.

9. The advisory committee specified by § 403(c) of the Radon Act to be comprised of representatives of Federal agencies concerned with the various aspects of indoor air quality is the Interagency Committee on Indoor Air Quality ("CIAQ"). This committee was formed in December 1983 and, upon passage of the Radon Act in 1987, evidently was designated to perform the Federal agencies' functions specified by the Act. The CIAQ is currently comprised of delegates from 16 member agencies. Each agency has one official CIAQ delegate member, and may designate one or more alternative delegates. The delegates from the EPA, CPSC, DOE and DHHS serve as co-chairs of the ICIAQ. See, "Structure and Operation

of the Interagency Committee on Indoor Air Quality," dated January 22, 1988.

10. In 1986 the EPA issued a draft of the "Final Guidelines for Carcinogen Risk Assessment" (51 FR 33992, Sept. 24, 1986). The guidelines emphasized full consideration of all relevant data and identification of strengths and weaknesses for each risk assessment. (See Attachment A.) The draft guidelines have been and still are under review and evaluation.

11. The EPA Risk Assessment Guidelines were intended to assist the agency in the evaluation of suspected carcinogens pursuant to the policies and procedures established in statutes administered by the EPA. The EPA guidelines emphasize that (i) assessments will give full consideration to all relevant scientific information, (ii) scientific information will be fully presented in agency risk assessment documents, and (iii) agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions and limitations as well as the scientific basis and rationale for each assessment. The EPA guidelines further expressly state:

The purpose of these guidelines is to promote quality and consistency of carcinogen risk assessment within the EPA and to inform those outside the EPA about its approach to carcinogen risk assessment. (51 F.R. 33993)

12. By virtue of the EPA's own pronouncements, there are two components of the EPA risk assessment process. The first relates to the uniform and consistent application of the EPA's own guidelines governing technical aspects of risk assessment. The second is the uniform, consistent and fair application of EPA procedures for involving and informing the public concerning ongoing risk assessments.

13. Presumably as part of the EPA's research efforts, the Office of Health and Environmental Assessment of the EPA's Office of Research and Development initiated the preparation of two preliminary draft reports dealing with the potential health risks associated with environmental tobacco smoke. The draft reports were subsequently entitled "Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children" and "Environmental Tobacco Smoke: A Guide to Workplace Smoking Policies" (hereinafter "Draft Reports"). These reports were purportedly written under the authority of the Radon Gas and Indoor Air Quality Research Act of 1986.

14. In June, 1988, the Indoor Air Division of the EPA initiated the Draft Workplace Smoking Policy Guide project purportedly "to provide information to policy makers on the technical and policy options for instituting workplace smoking policies. . . . It was allegedly felt that a sufficient body of

scientific information on the health effects of environmental tobacco smoke had already been developed to warrant a layman's guide to mitigating exposure to ETS." (June 25, 1990 Memorandum from William Rosenberg, Assistant Administrator of EPA, to Donald Barnes, Director of the SAB.) However, no evaluation of the scientific data had yet been undertaken by the EPA, when its Indoor Air Division decided to draft its Policy Guide.

15. Pursuant to EPA single source contracting, the initial Draft Policy Guide was prepared by Robert Rosner and Robin Simons of the Smoking Policy Institute ("SPI"). SPI is involved in implementing smoking bans in the workplace. (See Attachment B.)

16. Then, in 1989, EPA initiated the ETS risk assessment project that would purportedly look at prior and contemporary research concerning the health effects of passive smoking and "seek to classify ETS [Environmental Tobacco Smoke] ETS according to the Agency's carcinogen assessment guidelines and to estimate the extent of lung cancer and other respiratory effects from passive smoking to nonsmokers." (June 25, 1990 Memorandum from William Rosenberg, Assistant Administrator of the EPA, to Donald Barnes, Director of the SAB). This effort eventually resulted in the preparation of the ETS Draft Risk Assessment. This project was also purportedly accomplished under the authority of the Radon Gas and Indoor Air Quality Research Act of 1986.

17. In the spring of 1990, a consultant (Kenneth Brown) for EPA's Office of Health and Environmental Assessment (OHEA) completed preparation of a preliminary draft document on health risks reportedly associated with ETS. The draft advocated classification of ETS as Group A ("known human") carcinogen, purportedly under the EPA's Risk Assessment Guidelines.

18. Kenneth Brown was the principle author of the Draft Risk Assessment, and in fact prepared the initial draft. (See Draft Risk Assessment; transcript of December 4, 1990 IAQTHEC hearing, testimony of Steve Bayard.) However, one Dr. David Burns reviewed the early versions of the Draft Risk Assessment and may have participated in revising the ETS Draft Risk Assessment.

19. In May, 1990, ICF, Inc. was engaged to perform some work with respect to the ETS Draft Risk Assessment. (EPA contract with ICF.)

20. In May 1990, the Draft Risk Assessment was leaked to the media before any copies were available to the public and was the subject of a Los Angeles Times article. (See Attachment C.) Interestingly, at approximately the same time, the staff in the Office of Air and Radiation developed and distributed in

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internal EPA communications strategy outlining media plans for the draft ETS documents.

21. On June 25, 1990, the EPA formally released the Draft Risk Assessment on ETS; the Draft Workplace Smoking Policy Guide; and issued a notice of EPA public comment period and an indication of intent to pursue referral of the documents to the SAB.

22. Despite the fact that the EPA was currently actively reviewing its guidelines for carcinogen risk assessment in mid-1990, the EPA nonetheless issued in mid-1990, three major documents on health effects. These documents, issued in the form of review drafts, were the focal points of three separate risk assessment processes, and are identified as follows:

(i) EPA workshop will review draft, Health Assessment Document for Diesel Emissions, EPA/600/8-90/057A, July, 1990 (hereinafter "Diesel Emissions Review Draft");

(ii) EPA workshop review draft, Evaluation of the Potential Carcinogenicity of Electromagnetic Fields, EPA/600/6-90/005A, June, 1990 (hereinafter "EMF Review Draft");
and

(iii) EPA review draft, Health Effects of Passive Smoking: Assessment of Lung Cancer in Adults and Respiratory Disorders in Children, EPA/600/6-90/006A, May; 1990 (sometimes hereinafter "ETS Review Draft").

23. The EPA subsequently forwarded the Draft ETS Reports to the IAQTHEC. The EPA gave the IAQTHEC the charge to review the accuracy and completeness of the Risk Assessment and review whether the weight of the evidence supported the conclusion of the Draft Reports that environmental tobacco smoke causes cancer and other respiratory diseases. The IAQTHEC was then comprised of seven members; those persons were Dr. Morton Lippmann, Dr. Jan Stolwijk, Dr. Joan Daisey, Dr. Victor Laties, Dr. Jonathan Samet, Dr. Jerome Wesolowski and Dr. James Woods, Jr. However, for its purpose of reviewing the draft report, the SAB decided to expand the IAQTHEC by adding additional members. This expansion was purportedly accomplished so that the IAQTHEC would fulfill the representational requirements of the advisory group created by the Radon Gas and Indoor Air Quality Research Act of 1986.

24. Consequently, in July 1990, the SAB set about a process of identifying individuals to add to the IAQTHEC, for the purpose of reviewing the draft documents. Initial suggestions for panel membership were provided by EPA's Indoor Air Office, with input from James Repace. (11/26/90 letter from Donald Barnes to

Congressman Bliley; 10/25/91 letter from Administrator Reilly to Congressman Bliley.) The Tobacco Institute ("TI") presented to the EPA a list of independent scientists who would be appropriate consultants to be appointed to the IAQTHEC. (11/26/90 letter from Barnes to Bliley.) None of the scientists suggested by TI was selected to participate.

25. By July 1990, the EPA had issued its workshop review draft titled "Health Assessment Document for Diesel Emissions." (See Attachment A for a comparative analysis of the EPA's Draft Risk Assessment with respect to diesel emissions). This risk assessment involved an EPA-sponsored scientific workshop to obtain full, robust debate and input on the scientific issues. On July 25, 1990, Philip Morris specifically requested that EPA conduct one of its normal scientific workshops on ETS. The request was denied in writing by EPA on September 21, 1990.

26. The official public comment period on the ETS draft documents closed on October 1, 1990. Over 100 comments were submitted on both the Draft Risk Assessment and the Policy Guide. The comments on the Policy Guide were summarized for the EPA by Kenneth Brown -- the same consultant who prepared the Draft Risk Assessment. (See Attachment "D".)

27. On October 23-24, 1990 the SAB selected nine additional individuals to serve as members of the IAQTHEC (those persons were Dr. Neal Benowitz, Dr. William Blot, Dr. David Burns, Dr. Delbert Eatough, Dr. S. Katherine Hammond, Dr. Geoffrey Kabat, Dr. Michael Lebowitz, Dr. Howard Rockette, Jr. and Dr. Scott Weiss), to assist in analyzing the EPA's Draft Risk Assessment on ETS. None of the candidates suggested by the Tobacco Institute was appointed to the IAQTHEC. In fact, none of those persons was even contacted by the SAB. To the contrary, one-third of the newly appointed members were selected from lists submitted by anti-smoking organizations.

28. As thus constituted, none of the members of the IAQTHEC represented the viewpoints of the tobacco industry. The EPA has recognized the need to confine membership in the IAQTHEC to "knowledgeable experts who are free from legal and perceived conflict-of-interests," that "the deliberative process is generally not aided if extreme views are represented on the panel itself," and that "[c]learly, the SAB did not seek out individuals who are so identified with the 'ends of the spectrum'" on the issues concerning ETS.

29. The IAQTHEC, as reconstituted also did not meet the representational requirements of the Radon Act. On October 23-24, 1990, the SAB Executive Committee meeting was conducted as a closed meeting at which the public was denied the prior notice and denied access contemplated by the Federal Advisory Committee

Act, 5 U.S.C. App. 2 § 10. During the course of this closed meeting, Dr. David Burns was appointed a consultant of the IAQTHEC. This occurred despite the fact that just the previous day, Dr. Donald Barnes of the EPA acknowledged that Dr. Burns was not suitable for membership because of his demonstrated bias. Dr. Donald Burns was then a long-recognized anti-smoking advocate who had publicly stated his intention to see smoking behavior disappear from society.

30. On November 1, 1990, the EPA issued its charge to the SAB. (See Attachment E.) As it evolved, the scientific answers to the charge do not support the conclusions rendered by the SAB. (See Attachment F.)

31. On November 20, 1990, the EPA published a public notice of public meetings to be held December 4-5, 1990, in the Federal Register, at which time the IAQTHEC, as expanded by the EPA, would consider the draft document.

32. On December 4, 1990, the IAQTHEC commenced its public meeting in Arlington, Virginia, on the ETS Draft Risk Assessment and the Draft Workplace Smoking Policy Guide. Dr. Morton Lippmann, Chairman of the IAQTHEC, presided. Public comments were severely limited in number and duration. Some but not all comments by available then-attending scientists were received by the IAQTHEC.

33. Immediately after the meeting, Chairman Lippmann stated on December 5, 1991 that while he was speaking only for himself, there was somehow an SAB consensus that there was enough evidence to classify ETS as a Group A carcinogen, and there was even stronger evidence that ETS is associated with respiratory effects in children than the Draft Risk Assessment had reported. Dr. Lippmann terminated the hearing early (despite witnesses still seeking an opportunity to speak) to hold his press conference which was in fact coordinated by the EPA Press Office.

34. The Draft Risk Assessment Report and Workplace Smoking Guide were to then be submitted to SAB's Executive Committee. However, no additional meetings were held by the SAB/IAQTHEC committee and no additional opportunity for public testimony and comment was provided.

35. On April 18-19, 1991, the SAB Executive Committee approved, with only minor modifications, the IAQTHEC reports dealing with the ETS Draft Risk Assessment and the Draft Workplace Smoking Policy Guide; only relatively minor comments were made with respect to the Policy Guide. The SAB Executive Committee unanimously approved the IAQTHEC's report, which agreed with the conclusions of the Draft Risk Assessment that ETS is a cause of lung cancer in nonsmoking adults and should be classified as a

Group A carcinogen. The IAQTHEC report recommended revisions to the Draft Risk Assessment to be made by EPA. The Executive Committee authorized the IAQTHEC report to be submitted to the Administrator for EPA revision.

36. On April 23, 1991, the SAB Executive Committee delivered the IAQTHEC Draft Risk Assessment and Draft Policy Guide reports to the EPA Administrator for further revision by the EPA. The substantive analysis contained in the Draft Risk Assessment has been, and continues to be, sharply criticized.

37. On May 30, 1991, after an unauthorized release of a third ETS-related document, the Draft Technical Compendium, an article was published by the Associated Press stating that even though the final draft of the Technical Compendium had been completed in April, its public release had been delayed indefinitely. According to the article, the EPA had not approved the document and might never approve it.

38. On July 23-24, 1991, a discussion was scheduled by the SAB Executive Committee to determine whether the SAB should review the Technical Compendium. The Executive Committee voted not to review the Draft Compendium. This decision was purportedly based on the fact that the Compendium was not intended as an official EPA document. It was recommended by the SAB that the

chapters of the Compendium be published and thereby undergo a normal peer review before any issuance of the Compendium by the Agency. Of the eleven chapters, only one has been published.

39. On September 12-13, 1991, the IAQTHEC held an open meeting pursuant to the FACA for the purpose of reviewing the EPA's draft Final Exposure Assessment Guidelines dated August 8, 1991. The members of the IAQTHEC who participated in the meeting are Drs. Lippmann, Stolwijk, Daisey, Laties, Lioy, Samet, Wesolowski and Woods. No consultants to the IAQTHEC participated.

40. On October 31, 1991, the Oversight and Investigation Subcommittee of Congress held hearings at which Administrator Reilly and others testified concerning the general subject of EPA's compliance with the Clean Air Act. A copy of the Statement of Congressman Bliley is attached as Attachment "G".

41. Facts supporting arguments that the public interest has not been served by the EPA/SAB process and procedures relating to the draft documents include the following:

a. The EPA authorized the preparation and dissemination of a draft "Guide to Workplace Smoking Policies" on ETS prior to completion of scientific review by the SAB.

b. It is at least arguable that the EPA had no statutory authority to conduct a risk assessment of ETS.

c. The EPA has pursued development of an internal communications plan regarding dissemination of risk assessment results prior to finalization by the EPA's SAB.

d. The EPA's own Administrator's office has reviewed the draft Risk Assessment and found it lacking.

e. The SAB Committee included Dr. Burns on the Indoor Air Committee after the Executive Director had indicated that Dr. Burns was removed because he was biased. There is no record of such action as required by the Federal Advisory Committee Act. It is unclear exactly when and how the Executive Committee "voted" on the inclusion of Dr. Burns on the Committee. This suggests a violation of the Federal Advisory Committee Act, 5 U.S.C. App. 2 § 10.

f. Members of the SAB review Committee reviewed and commented on their own work. The consultant commissioned to write the risk assessment is a consultant to the SAB. He was also asked to prepare a profile of the comments submitted as part of the public record.

g. The EPA generated a new "Appendix E" regarding childhood exposure. It appears that the new "Appendix E" may have been transmitted to the SAB without benefit of public comment. By transmitting the additional documents to the SAB without public scrutiny, the Office of Research and Development and the Office of Air and Radiation may have exposed a practice within the EPA of transmitting EPA documents to the Committee that have not been reviewed by the public.

h. Lists of potential SAB members were submitted to the EPA, and three members on their list were selected whereas no person was selected from the Tobacco Institute list. Because "lists" of potential SAB Committee members are acquired through various means, from the industry to internal EPA programs lists to direct nominations from the current SAB members, a question is raised whether the lists submitted by different sectors are treated evenly by the Designated Federal Official ("DFO") as decisions are made on potential candidates for Committee membership.

i. The EPA SAB Executive Committee will eventually review its own risk assessment guidelines. Risk assessments conducted before that review are premature and inappropriate from a regulatory context.

j. OMB has called EPA's and the Federal Government's risk assessment process into question, particularly at EPA for their use of impractical models for assessing cancer risks and going beyond risk assessment into risk management by mixing policy and science questions and using conservative assumptions.

k. There has been no demonstrated method for ensuring accountability among SAB staff in selecting consultants and in allowing their own predilections and those of the consultants to come into account.

l. There are serious regulatory questions about focusing upon weak association relative risks. ETS, as reported in the draft risk assessment, is an easily confounded, weak association.

m. The "Workplace Smoking Policy Guide" was authored by the Smoking Policy Institute, an EPA contractor, which is in the business of implementing no-smoking policies in businesses.

n. Kenneth Brown, the author of the draft ETS Risk Assessment, was commissioned to write the report by the EPA Office of Research and Development (using funding from the

Office of Air and Radiation). Dr. Brown is currently on the list of SAB consultants. Dr. Brown has also been commissioned to prepare the "profile" of the public comments on the draft Risk Assessment.

o. Dr. Samet of the IAQTHEC (and possibly others) authored chapters of the Draft Technical Compendium on ETS. Also, there has been reference made that several members of the Committee at some point in the drafting of the draft ETS Risk Assessment, either commented extensively or were a part of the external review team that reviewed the document prior to its public release.

p. The EPA has not pursued SAB oversight as to this review panel, pursuant to EPA established uniform administrative guidelines as is required under 5 U.S.C. § 8.

q. The EPA, without explanation, has established an SAB Panel which extends membership beyond the standing Science Advisory Board Committees of the EPA.

r. Under the Federal Advisory Committee Act, 5 U.S.C. App. 2, § 1 et seq., membership of an advisory committee must be "fairly balanced" and "independent." Membership of the EPA's IAQTHEC [or SAB] meets neither of those standards.

Neither does the IAQTHEC meet the representational requirements for the mandatory advisory group created by the Radon Act.

s. The Executive Committee of the SAB apparently voted to include Dr. David Burns on the IAQTHEC following reports that the SAB staff director believed that Dr. Burns should not participate on the ETS review panel because of his bias on the subject. The SAB Executive Committee voted in an "informal" session during their meeting October 23-24, 1990 to include Dr. Burns on the IAQTHEC.

t. Several members of the IAQTHEC who participated at some point in drafting the ETS Risk Assessment, later either commented extensively or were a part of the external review team that reviewed the document prior to its public release.

u. The EPA generated a new "draft report with a detailed description and analysis of 26 studies" on childhood exposure to ETS. This document was transmitted to the SAB without having been available during the public comment period for public review. It discussed these 26 studies, but did not include others which do not support the conclusions of the ETS draft documents. Without any public review, the EPA staff asked that it be considered for attachment to the final report as "Appendix E."

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v. The public notice identifying the SAB meeting dates of December 4-5, 1990, was published in the Federal Register on Tuesday, November 20, 1990, only fourteen days (including the intervening two weekends and Thanksgiving holiday), prior to the meeting. This notice does not comport the notice provided by EPA on other health assessment documents.

w. The Office of Management and Budget ("OMB") has questioned EPA's and the Federal Government's risk assessment programs, particularly at EPA, because of the use of impractical models for assessing cancer risks and because of the tendency to go beyond risk assessment into risk management by mixing policy and science questions against the background of ultra-conservative assumptions. Internally, EPA staff have asked the SAB Executive Committee to review the Agency's risk assessment guidelines. It defies reason and logic for the Agency to proceed with certain risk assessments while their guidelines for risk assessment are at the same time being criticized and reviewed.

x. There does not appear to be any EPA regulatory guidelines for the use by the Agency of the controversial meta-analysis statistical technique in assessing epidemiological evidence, particularly for risks which report, at best, a very weak association. A relative risk of 1.3,

achieved through the questionable use of meta-analysis, was reported in the EPA review draft on ETS.

y. The SAB itself has confirmed that there is no apparent method for ensuring accountability among SAB staff in the selection of SAB consultants and for preventing the staff's own predilections and those of the consultants to figure prominently in SAB consideration. The SAB lacks procedures to prevent a collegial relationship with the EPA staff offices which request SAB review of their documents. If, as the designated Federal officer ("DFO") for the ETS issue indicated, the SAB staff has indeed asked those EPA program staff involved in funding and preparing the documents for SAB review the fundamental question, "what is it that the program office is trying to do with the document that the SAB will review?", the lack of appropriate independence is apparent. Further, the "charge" which directs the SAB review of the documents was, in this case, prepared by the program staff. No mechanisms are present within the Agency to ensure that the SAB and program offices do not bias the final composition of the SAB Committees, the charge to the SAB Committee reviewing the reports and ultimately, the final SAB report. Such collegial interaction between the program and SAB offices gives rise to an undue deference toward accomplishing previously established EPA program office goals.

z. With regard to the relationship between ETS and other chemicals, the EPA stated in its August 1989 Report to Congress on Indoor Air Quality that it would explore a possible inter-relationship between ETS and radon. Even though the EPA consultant who authored the draft risk assessment also conducted a study on the possible interaction between ETS and radon (in October 1989, at the annual meeting of the Society for Risk Analysis, the EPA consultant and author of the ETS risk assessment, Dr. Kenneth Brown, presented a paper entitled, "The Influence on Lung Cancer from Radon in the Home" which apparently reached the above-referenced conclusions) which apparently concluded that ETS lowers the dose of radon exposure, this study was not discussed in, or otherwise included as part of, the draft risk assessment. Further, this document still does not appear to be available to the public. However, in the charge to the SAB, the SAB was asked whether the interaction of ETS and radon should be discussed and whether a dose-response model should be established.

aa. The EPA acknowledged in the draft Risk Assessment that comments were received prior to the release of the draft on radon and on the possible effects of ETS in the workplace but these comments were not made available to the public.

There was no other reference to the substance of these comments in the draft.

42. The EPA/SAB work on the Draft Documents further contravenes the provisions of the Regulatory Program of the United States: